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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/923,023 | 08/06/2001 | Camilo Colaco | GJE-6082D1 | 9122 |
| 23557 | 7590 | 02/23/2004 | EXAMINER | |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669 | | | KRISHNAN, GANAPATHY | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1623 | | |
| DATE MAILED: 02/23/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/923,023 | COLACO, CAMILO | |
| | Examiner | Art Unit | |
| | Ganapathy Krishnan | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 14-29 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicant's election of Group I, claims 1-13 and maltooligosaccharides as species A and peptide/protein mimetic as species B for prosecution in the response filed November 3, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 14-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed November 3, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites modified glycoside. In the absence of the specific moieties intended to effectuate modification by substitution or attachment to the chemical core claimed, the term modified renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate modification,

requisite to identifying the composition of matter claimed. For the purpose of prosecution modified is interpreted to mean anything which effects a change in the chemical core claimed.

Claim 8 recites derivative. In the absence of the specific derivatization to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of derivatized of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosner et al (WO 96/03978).

Rosner teaches glassy delivery vehicles loaded with a wide variety of substances. The invention encompasses glassy vehicles formed from hydrophobically derivatized carbohydrates and guest substances such as steroid hormones, peptides, peptide mimetics and antibiotics (bioactive substances, page 8, lines 1-31). The carbohydrates of the invention include glycosides selected from sugar alcohols and polyalcohols. The specific hydrophobically derivatized carbohydrates of their invention with the hydroxy group derivatized in the form of an ester are

trehalose ocataacetate (Y is glucose, n is 1 and X is glucose, a six carbon monosaccharide polyalcohols), sucrose octacetate (Y is glucose, n is 1 and X is fructose, a six carbon polyalcohols), and the ether derivative tetra-O-methyl trehalose. All of these fit the general structure (Y)n-X wherein n is 1 in claim and the limitations of claims 2 and 6 (Y is a saccharide subunit, n = 1 and X is a 5 or 6 carbon polyalcohols, and are ester or ether derivatives of a glycoside, page 21, lines 20-35). Their composition may further contain acceptable glass that includes carboxylate, nitrate, sulfate, bisulfate and combinations thereof, which meets the limitations of claim 8 (page 28, lines 26-32).

Guest substances incorporated in the composition of Rosner's invention include bioactive materials and pharmaceutical agents. Such agents include bacteria, proteins and peptides, peptide mimetics, hormones, viruses, lipids, oligo and polysaccharides, nucleic acids and protein nucleic acid hybrids, which meets the limitations of claim 10 and 11. Proteins include enzymes, growth hormones, growth factors, insulin, monoclonal antibodies and cytokines which meets the limitations of claim 12. The composition also includes immunogenic substances like viruses, antigens, nucleotide vectors encoding antigens bacteria antigens adjuvants and haptens, which meets the limitations of claim 13 (page 29, line 29 through page 32, line 15). The solid dose forms are selected from a group that includes all of the forms recited in instant claim 9 (page 78, lines 14-19).

Conclusion

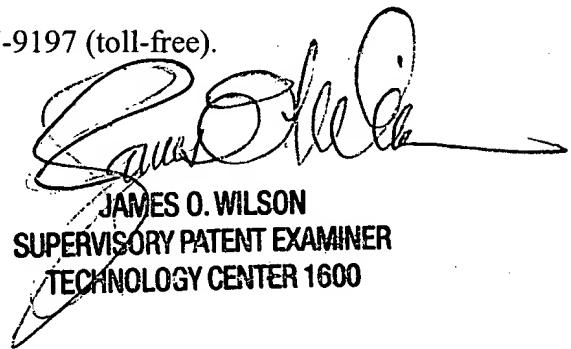
Claims 1-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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